K041421

AUG 2 6 2004

510(k) Summary :

Proprietary Name:	Stryker® TCP Putty
Common Name:	Bone Void Filler
Classification Name:	Resorbable calcium salt bone void filler device
Reference:	21 CFR 888.3045
Device Product Code:	MQV – Filler, Calcium, Preformed Pellet
Submitted By:	Stryker Biotech 35 South Street Hopkinton, MA 01748
Contact Information:	Sharon McDermott Regulatory Specialist Phone: (508) 416-5200 Fax: (508) 544-6150
Date Summary Prepared:	27 May 2004

Device Description:

Stryker® TCP Putty is an absorbable bone void filler composed of porous tri-calcium phosphate granules and carboxymethylcellulose, sodium (CMC) putty additive. It is an osteo-conductive implant with a multidimensional porosity similar to human cancellous bone and acts as a scaffold for the in-growth of new bone and other connective tissues. The putty consistency allows the shape of the implant to conform to the defect, maximizing direct contact with viable host bone.

Intended Use:

Stryker® TCP Putty is indicated as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated for surgically created osseous defects or osseous defects resulting from traumatic injury. It should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Stryker® TCP Putty is intended to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine, and pelvis). Following placement in the bony void or gap, Stryker® TCP Putty is resorbed and replaced with bone during the healing process.

Summary of substantial equivalence:
The intended use, materials, device performance and physical characteristics of Stryker® TCP Putty are substantially equivalent to those found in one or more of the following predicate devices.

K994337: Vitoss™ Scaffold Synthetic Cancellous Bone Void Filler_(Orthovita, Inc.)

K021963: BIOSORB® Resorbable Void Filler (Sciences et Bio Materiaux)

K010555: JAX™ Bone Void Filler (Smith & Nephew, Inc.)

K020895: Allomatrix Putty (Wright Medical Technology, Inc.)

Testing Summary

Laboratory testing and animal testing were provided to characterize the subject device and to allow comparison of its characteristics to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2004

Ms. Sharon McDermott
Regulatory Affairs Specialist
Stryker Biotech
35 South Street
Hopkinton, MA 01748

Re: K041421
Stryker® TCP Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: May 27, 2004
Received: May 28, 2004

Dear Ms. McDermott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

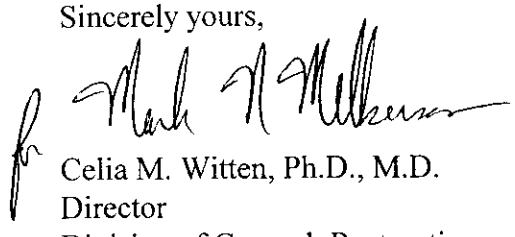
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041421

Device Name: Stryker® TCP Putty

Indications For Use:

TCP Putty is indicated as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated for surgically created osseous defects or osseous defects resulting from traumatic injury. It should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

TCP Putty is intended to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine, and pelvis). Following placement in the bony void or gap, the tri-calcium phosphate scaffold is resorbed and replaced with bone during the healing process.

Prescription Use: X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041421